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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,507	11/05/2003	Ali Amara	03495.0301	6288

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/20/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/700,507	AMARA ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24,27-29,31-34,36,40,81,82,91,94-96,98-102,104,105,110 and 111* is/are pending in the application.

4a) Of the above claim(s) *81,82,104 and 105* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24,27-29,31,40,91,94-96 and 98* is/are rejected.

7)☒ Claim(s) *32-34,36,99-102,110 and 111* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response filed September 26, 2006 is acknowledged and entered. Claims 24, 27-29, 31-34, 36, 40, 81, 82, 91, 94-96, 98-102, 104, 105, 110 and 111 are pending. Claims 81, 82, 104 and 105 are withdrawn from consideration, being drawn to non-elected subject matter. This Office action is non-final in view of the new grounds of rejection set forth below. Any inconvenience is regretted.

Response to Amendment

The rejection of claims 24, 25, 27-29, 31-34, 36, 40, 91, 92, 94-96, 98-103, 110 and 111 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, is withdrawn in view of Applicant's persuasive arguments.

The rejection of claims 24, 25, 27, 29, 31-34, 40, 91, 92, 94, 96, 98-101 and 103 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of Applicant's persuasive arguments.

The rejection of claims 24, 27-29, 31-34, 36, 40 and 110 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is withdrawn in view of Applicant's persuasive arguments.

Claims Summary and Interpretation

The claims are drawn to a method of treating a CMV infection of a mammal or inhibiting entry of a CMV virus into a cell of a mammal, comprising administering to the mammal a

molecule that specifically binds to a DC-SIGN receptor. The molecule is administered in an amount sufficient to inhibit the binding of the CMV virus to the DC-SIGN receptor. Specifically, the molecule that binds to the DC-SIGN receptor is a CMV envelope glycoprotein B, or a binding moiety thereof. In another embodiment, the molecule that binds to the DC-SIGN receptor is an antibody, Mab1B10.2.6.

In another embodiment, the claims are drawn to a method of treating an HIV infection or inhibiting entry of an HIV virus into a cell of a human, comprising administering a binding moiety of the CMV envelope glycoprotein B that binds to the DC-SIGN receptor, thus inhibiting the binding of HIV gp120 to the DC-SIGN receptor.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(*New Rejection*) Claims 24, 27-29, 31, 91, 94-96 and 98 are rejected under 35 U.S.C. 102(b) as being anticipated by Pass *et al.* (*The Journal of Infectious Diseases*, 1999, 180:970-975, "Pass"). The claims are summarized above. Pass discloses a subunit CMV composition comprising recombinantly produced glycoprotein B and an adjuvant (abstract). The composition was administered to humans (page 970, second column). The CMV antigen comprises the entire extracellular glycosylated domain and the entire intracellular domain of envelope glycoprotein B (page 970, second column, "Vaccine formulation and administration").

Although Pass does not teach that their recombinantly produced CMV gB has the capability to bind to DC-SIGN, the gB is entirely expected to bind DC-SIGN. By administering Pass' gB to humans, DC-SIGN is bound by gB and thus inhibits CMV infection. Therefore, Pass' method anticipates the instantly claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(*New Rejection*) Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pass *et al.* (*The Journal of Infectious Diseases*, 1999, 180:970-975, "Pass") in view of Cunningham *et al.* (*The New England Journal of Medicine*, 1998, 339(4):236-244, "Cunningham"). The claim is drawn to a method of treating HIV by administering CMV glycoprotein B to an individual. The teachings of Pass are summarized above. Pass does not teach the treatment of HIV. However, it would have been obvious to apply Pass' method to an HIV patient susceptible to or infected with CMV. One of ordinary skill in the art would have been motivated to treat CMV infection in an HIV patient because CMV is an opportunistic pathogen that routinely infects immuno-suppressed HIV patients, evidenced by Cunningham. Cunningham teaches that CMV retinitis affects 30 to 40% of HIV-positive patients in developed countries whose CD4+ T-cell counts have fallen below 100 cells/mm^3 (page 240, second column). One would have had a reasonable expectation of success that using Pass' CMV

treatment would have worked with HIV patients that are susceptible to infection with CMV, given the high prevalence of CMV infection in HIV patients.

Although Pass does not teach that their recombinantly produced CMV gB has the capability to bind to DC-SIGN, the gB is entirely expected to bind DC-SIGN. By administering Pass' gB to humans infected with HIV, DC-SIGN is bound by gB and thus inhibits CMV infection. Further, according to Applicant, CMV gB will also inhibit HIV infection. Therefore, the claimed method is obvious over Pass in view of Cunningham.

Conclusion

Claims 32, 33, 34, 36, 99-102, 110 and 111 are objected to for depending (ultimately) from rejected claims. The subject matter of claims 32, 33, 34, 36, 99-102, 110 and 111 is free of the prior art of record.

Geijtenbeek *et al.* (*Cell*, 2000, 100:587-597, "Geijtenbeek") discloses that monoclonal antibodies AZN-D1 and AZN-D2 bind to DC-SIGN (page 588, second column). These antibodies inhibit the binding between HIV gp120 and dendritic cells. Geijtenbeek teaches that DC-SIGN efficiently recruits HIV-1 and facilitates HIV-1 infection of CD4+ T cells by a novel in trans mechanism (page 592, second column, "Discussion"). Geijtenbeek suggests that inhibition of HIV-1 in the presence of anti-DC-SIGN antibodies suggests that interfering with the gp120-DC-SIGN interaction during the capture phase of dendritic cells in the mucosa or during dendritic cells/T cells interactions in lymphoid organs could inhibit dissemination of the virus (page 595, second column, last paragraph). The Office notes that although HIV patients are routinely infected with the opportunistic pathogen, CMV, Geijtenbeek does not teach or

fairly suggest that CMV infection could also be treated using the anti-DC-SIGN antibodies. Any improvement in a CMV infection of an HIV patient would have been considered an indirect result of an improvement of the HIV infection (if the antibodies had the desired effect *in vivo*).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B. Chen 12/15/06

STACY B. CHEN
PRIMARY EXAMINER